UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS GRANUFLO/NATURALYTE DIALYSATE PRODUCTS LIABILITY LITIGATION	**MDL NO. 1:13-MD-2428-DPW**
This Document Relates to:	**JURY TRIAL DEMANDED**
All Cases	

MASTER COMPLAINT AND DEMAND FOR JURY TRIAL

The Plaintiffs' Executive Committee ("PEC") and the Plaintiffs' Steering Committee ("PSC") file this *Master Complaint and Demand for Jury Trial* ("*Master Complaint*") as an administrative device. The intent of the filing of the Master Complaint is to set forth the claims that individual Plaintiffs and/or the estates and/or heirs of deceased persons may assert against Defendants in this litigation through the adoption of this Master Complaint by such individual Plaintiffs and/or the estates and/or heirs of deceased persons as their own Complaint. The adoption of this Master Complaint will occur through the filing of a *Short Form Complaint* where the individual Plaintiffs and/or the estates and/or heirs of deceased persons will incorporate this Master Complaint into their specific case. An implementing Case Management Order will permit the filing of this Master Complaint and its adoption by the filing of a *Short Form Complaint* in each specific case.

I. SUMMARY OF THE CASE

1. This action arises from the use of NaturaLyte® and/or GranuFlo® Dry Acid Concentrates ("NaturaLyte" and/or "GranuFlo") in the dialysis treatment of persons and the resultant injuries and deaths suffered by such persons that were caused by NaturaLyte and/or

GranuFlo. The products that are the subject of the litigation are any dry acid concentrate, whether it be labeled by the Defendants as "GranuFlo" or "NaturaLyte" or both, yielding a concentration of acetate greater than 4 meq/L when put into solution for use in dialysis, by including sodium diacetate in the product's formulation. These products are described hereafter collectively as "NaturaLyte and/or GranuFlo".

2. As a result of the defective nature of NaturaLyte and/or GranuFlo and Defendants' failure to properly label and warn about their products, persons who were given GranuFlo and/or NaturaLyte products as part of their dialysis treatment, including the living Plaintiffs and the deceased persons who are represented by their estates and/or heirs in this MDL, had significant health problems including but not limited to cardio pulmonary arrest, and/or sudden cardiac arrest or death.

3. Defendants concealed their knowledge of the dangers of NaturaLyte and/or GranuFlo from the living Plaintiffs and from the deceased persons who are represented by their estates and/or heirs, their health care providers, other consumers, and the medical community. Specifically, at all relevant times in this lawsuit, Defendants knew or should have known of the dangers of NaturaLyte and/or GranuFlo yet they failed to adequately inform Plaintiffs, the deceased persons who are represented by their heirs and/or estates, consumers, the prescribing medical community, and dialysis providers that NaturaLyte and/or GranuFlo presented the risk of and caused serious injuries and death.

II. PARTIES

A. PLAINTIFFS

4. This *Master Complaint* is filed for, and on behalf of all living Plaintiffs in this MDL, and if applicable, Plaintiffs' spouses, children and wards, and on behalf of decedents, and the administrators and/or executors of decedent Plaintiffs' Estates.

5. Plaintiffs are living individuals, and/or represent the Estate or interests of deceased or now incompetent individuals, who were administered NaturaLyte and/or GranuFlo for dialysis treatment and as a direct and proximate result of such administration of NaturaLyte and/or GranuFlo, suffered severe injuries and/or death, and damages therefrom.

B. DEFENDANTS

6. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

7. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States.

8. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has transacted and conducted business throughout the United States.

9. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States.

10. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. derives substantial revenue from interstate commerce throughout the United States.

11. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a corporation organized under the laws of the State of New York having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

12. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA is a major provider of renal care products. It provides products for chronic kidney disease and it manufactures and distributes a variety of dialysis products and equipment, including dialysis machines, dialyzers and other dialysis-related supplies.

13. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States.

14. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA has transacted and conducted business throughout the United States.

15. Defendant FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold, and/or distributed throughout the United States.

16. Defendant FRESENIUS USA, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451. Defendant FRESENIUS USA, Inc manufactures and distributes equipment and disposable products for the treatment of kidney failure by dialysis.

17. Defendant FRESENIUS USA, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

18. Defendant FRESENIUS USA, INC. has transacted and conducted business throughout the United States.

19. Defendant FRESENIUS USA, INC. has derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold and/or distributed throughout the United States.

20. Defendant FRESENIUS USA MANUFACTURING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

21. Defendant FRESENIUS USA MANUFACTURING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

22. Defendant FRESENIUS USA MANUFACTURING, INC. has transacted and conducted business throughout the United States.

23. Defendant FRESENIUS USA MARKETING, INC. is a corporation organized under the laws of the State of Delaware having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

24. Defendant FRESENIUS USA MARKETING, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

25. Defendant FRESENIUS USA MARKETING, INC. has transacted and conducted business throughout the United States.

26. Defendant FRESENIUS USA MARKETING, INC. has derived substantial revenue from goods and products used throughout the United States.

27. Defendant FRESENIUS USA MARKETING, INC. expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States.

28. Defendant FRESENIUS USA SALES, INC. is a corporation organized under the laws of the State of Massachusetts having its headquarters and principal place of business at 920 Winter Street, Waltham, Massachusetts, 02451.

29. Defendant FRESENIUS USA SALES, INC. at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States.

30. Defendant FRESENIUS USA SALES, INC. has transacted and conducted business throughout the United States.

31. Defendant FRESENIUS USA SALES, INC. has derived substantial revenue from goods and products used throughout the United States.

32. Defendant FRESENIUS USA SALES, INC. expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States.

33. Upon information and belief, defendants FRESENIUS USA, INC, FRESENIUS USA MANUFACTURING, INC., FRESENIUS USA MARKETING, INC., and FRESENIUS USA SALES, INC. are wholly owned subsidiaries of defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC. d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

34. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

35. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, a partnership limited by shares, was formerly known as FRESENIUS MEDCIAL CARE AG, a stock corporation. FRESENIUS MEDICAL CARE AG & CO. KGaA is the same legal business entity as FRESENIUS MEDICAL CARE AG.

36. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA is and was at all relevant times the parent company of defendants FRESENIUS MEDICAL CARE HOLDINGS, INC. and/or FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA.

37. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling, and/or distributing, NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

38. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has transacted and conducted business throughout the United States, including this judicial district.

39. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

40. Defendant FRESENIUS MEDICAL CARE AG & CO. KGaA expected or should have expected its acts to have consequences within this judicial district; and, derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

41. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is a corporation organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

42. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is the general partner of defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, and is responsible for the management of defendant FRESENIUS MEDICAL CARE AG & CO. KGaA.

43. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG was the majority voting shareholder of FRESENIUS MEDICAL CARE AG & CO. KGaA, when it was known as FRESENIUS MEDICAL CARE AG, and was responsible for the management of

defendant FRESENIUS MEDICAL CARE AG & CO. KGaA, when it was known as FRESENIUS MEDICAL CARE AG.

44. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

45. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG has transacted and conducted business throughout the United States, including this judicial district.

46. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

47. Defendant FRESENIUS MEDICAL CARE MANAGEMENT AG is and was at all times relevant herein a wholly owned subsidiary of defendant FRESENIUS SE & CO. KGaA.

48. Defendant FRESENIUS SE & CO. KGaA is a partnership limited by shares organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

49. Defendant FRESENIUS SE & CO. KGaA was formerly known as FRESENIUS SE, which was formerly known as FRESENIUS AG. Defendant FRESENIUS SE & CO. KGaA is the same legal business entity as FRESENIUS SE and FRESENIUS AG.

50. Defendant FRESENIUS SE & CO. KGaA at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting,

selling and/or distributing NATURALYTE and/or GRANUFLO throughout the United States, including this judicial district.

51. Defendant FRESENIUS SE & CO. KGaA has transacted and conducted business throughout the United States, including this judicial district.

52. Defendant FRESENIUS SE & CO. KGaA has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

53. Defendant FRESENIUS SE & CO. KGaA expected or should have expected its acts to have consequences within this judicial district; and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district.

54. Defendant FRESENIUS MANAGEMENT SE is a corporation organized under the laws of Germany having its headquarters and principal place of business at Else-Kröner Str. 1, 61352 Bad Homburg, Germany with a postal address of 61346 Bad Homburg, Germany.

55. Defendant FRESENIUS MANAGEMENT SE is the general partner of FRESENIUS SE & CO. KGaA and is responsible for the management of defendant FRESENIUS SE & CO. KGaA.

56. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGaA when it was known as FRESENIUS SE, and was responsible for the management of defendant FRESENIUS SE & CO. KGaA, when it was known as FRESENIUS SE.

57. Defendant FRESENIUS MANAGEMENT SE was the majority voting shareholder of FRESENIUS SE & CO. KGaA when it was known as FRESENIUS AG, and was responsible for the management of defendant FRESENIUS SE & CO. KGaA, when it was known as FRESENIUS AG.

58. Defendant FRESENIUS MANAGEMENT SE at all times relevant herein was in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing NATURALYTE and/or GRANULFO in the stream of commerce for use by the public, including Plaintiffs.

59. Defendant FRESENIUS MANAGEMENT SE has transacted and conducted business throughout the United States, including this judicial district.

60. Defendant FRESENIUS MANAGEMENT SE has derived substantial revenue from goods and products used throughout the United States, including this judicial district.

61. Defendant FRESENIUS MANAGEMENT SE expected or should have expected its acts to have consequences within this judicial district and derives substantial revenue from interstate commerce transacted throughout the United States, including this judicial district. All defendants are hereinafter referred to collectively as "Defendants" or "Fresenius".

62. At all relevant times herein, all Defendants were in the business of promoting, manufacturing, labeling, and/or distributing NaturaLyte and/or GranuFlo. Defendants do business throughout the United States and at all relevant times hereto, marketed, promoted, warranted and/or sold NaturaLyte and/or GranuFlo in this judicial district.

63. Defendants do not include any health care providers, any physician, hospital, health maintenance organization, dialysis centers, ambulatory surgical center, long-term care facility, registered or licensed practical nurse, pharmacist, physician-in-training, or any other person or entity that provides health care.

III. JURISDICTION AND VENUE

64. Federal subject matter jurisdiction in the constituent actions is based upon 28 U.S.C. § 1332(a), in that in each of the constituent actions there is complete diversity among Plaintiffs and Defendants and the amount in controversy exceeds $150,000.

65. Defendants have significant contacts with this federal judicial district and the one identified in the *Short Form Complaint* filed by each Plaintiff, such that they are subject to the personal jurisdiction of both this Court and the Court indentified in the *Short Form Complaint.*

66. A substantial part of the events and omissions giving rise to Plaintiffs' causes of action occurred in this federal judicial district and the one identified in the *Short Form Complaint.*

67. Pursuant to 28 U.S.C. § 1391(a), venue is proper in this district and the district identified in the *Short Form Complaint.*

IV. FACTUAL ALLEGATIONS

A. DIALYSIS GENERALLY

68. Defendants designed, manufactured, labeled, promoted, distributed, marketed, and/or sold NaturaLyte and/or GranuFlo. These concentrates are used during hemodialysis procedures.

69. The kidneys have important roles in maintaining health. When healthy, the kidneys clean the body's blood by maintaining the body's internal equilibrium of water and minerals (sodium, potassium, chloride, calcium, phosphorus, magnesium, sulfate). The acidic metabolism end-products that the body cannot get rid of via respiration are also excreted through the kidneys.

70. When kidneys fail, patients need a treatment to replace the work that the failed

kidneys did. Treatment includes either a kidney transplant or dialysis.

71. Dialysis is a method of treating acute and chronic kidney disease, especially where conservative treatment has been judged inadequate.

72. Dialysis is a procedure used to clean the blood in patients who have suffered end-stage renal disease (also known as renal failure or kidney failure).

73. There are two types of dialysis: peritoneal dialysis and hemodialysis. Hemodialysis is the most common way to treat advanced kidney failure and is often used to treat acute kidney failure.

74. Patients receive hemodialysis in a dialysis center, at home or in a hospital. Many people receive hemodialysis treatments three times per week in sessions of three to five hours each. This is known as conventional hemodialysis.

75. The procedure can help patients carry on an active life despite failing kidneys.

76. The goal of hemodialysis is to replace the functions of the patient's non-working kidneys. These functions include the removal of waste products that build up in the blood such as creatinine and urea; the appropriate adjustment of electrolyte levels (including potassium, calcium, and sodium); the correction of the acidosis (acid state) that tends to develop in these patients; and the removal of excess water that tends to accumulate in kidney failure patients.

77. Acidosis is an increased acidity in the blood as a result of the body's inability to excrete acid due to kidney failure.

78. Acidosis is a typical occurrence for patients in kidney failure.

79. Severe acidosis can lead to shock or death.

80. Dialysis attempts to correct an acidotic state, in part, by adding bicarbonate to the patient's blood.

81. The opposite of acidosis is alkalosis where a patient's blood has excess base (alkali).

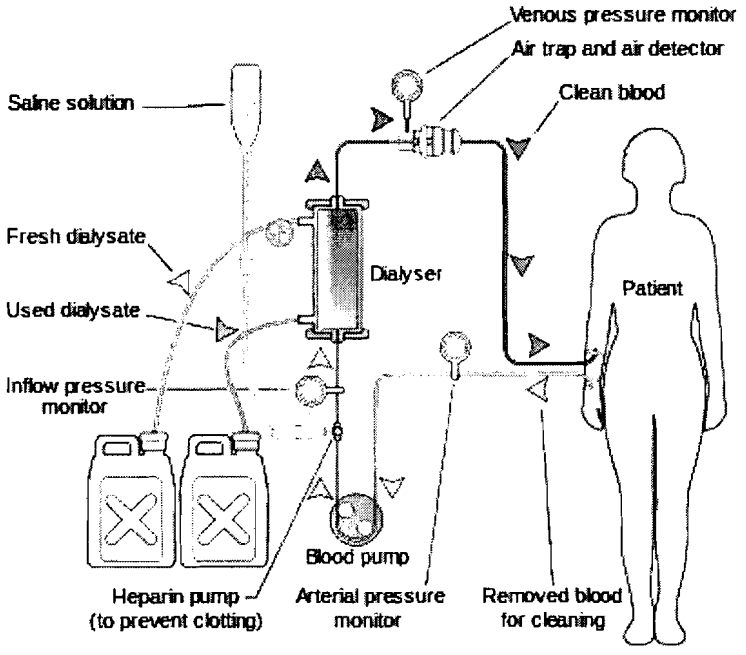
82. Alkalosis is caused by too much bicarbonate in the blood.

83. Symptoms of alkalosis include confusion, tremors, light-headedness, muscle twitching, nausea, vomiting, numbness or tingling, in the face, hands or feet.

84. Alkalosis can cause a patient to experience seizures, severe breathing difficulties, cardiac arrhythmias and/or death.

85. The keys of dialysis are 1) removal of waste products from the body; 2) the promotion of electrolyte balance in the blood; and 3) the addition of bicarbonate to the patient's blood to correct acidosis.

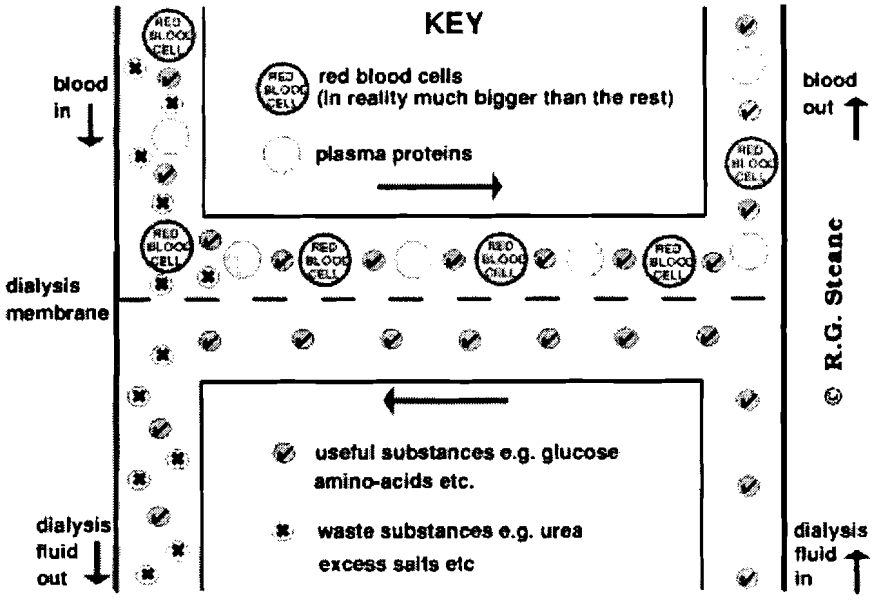
86. A person undergoing hemodialysis is connected to a hemodialysis machine (dialyzer) and then blood is removed from the body. Blood from a patient's artery circulates through the dialyzer and is returned to the body through a vein.



87. In the dialyzer, the blood passes through tiny tubes made of a semi-permeable membrane. Surrounding these tubes and flowing in the opposite direction from the blood (but not mixing with the blood itself) is a liquid solution known as dialysate. The semi-permeable membrane has tiny pores that allow small molecules to cross or diffuse through the membrane.

88. Diffusion is the process whereby random molecular motion causes a substance to go from an area of higher concentration to an area of lower concentration. Diffusion is a major physical activity, amongst other physical activities in the dialysis process.

89. During hemodialysis, the blood is pumped through the dialyzer in one direction and the dialysate is pumped in the opposite direction. Since the dialysate solution contains none of the waste products that are in the patient's blood (urea and creatinine), those waste products naturally diffuse through the membrane into the dialysate solution and are removed from the blood.



90. Depending on the electrolyte balance of the patient, the nephrologist may order a particular dialysate solution containing specific amounts of potassium, sodium, magnesium, and calcium.

91. Thus, for example, if a patient has a relatively high potassium level, the nephrologist may order a lower potassium solution to be utilized in the dialysate so that more potassium will diffuse across the membrane out the patient's blood and thus restore a proper electrolyte balance.

92. After several hours on the dialysis machine, and with this process of diffusion ongoing continuously, the patient's blood is cleaned of its excess waste products and presumably has had its electrolyte balance reestablished.

93. The dialysate used during dialysis is a mixture of 1) a bicarbonate concentrate and 2) an acid concentrate (Granuflo and/or NaturaLyte are the acid concentrate portions). The dialysate (bicarbonate and acid solutions) then flows through the dialyzer and interacts with the patient's blood.

94. Bicarbonate concentrate is used on all dialysis patients, but the amount of bicarbonate a patient receives can be adjusted.

95. Patients in renal failure tend to become acidotic, and that problem is corrected primarily by adding bicarbonate to their blood. Therefore, all dialysate solutions contain bicarbonate to correct the naturally occurring acidosis in patients in renal failure.

B. NATURALYTE AND GRANUFLO

96. NaturaLyte and/or Granuflo are acid concentrates used in the creation of dialysate.

97. GranuFlo and/or NaturaLyte have been on the market for many years and are unique in the dialysis treatment world in that they contain sodium diacetate. Through this formulation, GranuFlo and/or NaturaLyte increase the amount of acetate in dialysate (the fluid

and solutes in a dialysis process that flow through the dialyzer machine) compared to more traditional formulations made with acetic acid.

98. Defendants engaged in the design, manufacture, production, testing, study, research, inspection, mixture, labeling, marketing, advertising, sales, promotion and/or distribution of NaturaLyte and/or GranuFlo. These concentrates are used during hemodialysis procedures.

99. Defendants manufacture, sell, and promote dialysis products in both the U.S. and the world. Their market share is the largest in both the U.S. and the world.

100. Defendants manufacture, label, promote, and sell dialysis machines and dialysis products including but not limited to dialyzers, blood lines, needles, and dialysis concentrate.

101. Fresenius facilities use Defendants' dialysis products. Defendants also sell and market their products to other dialysis facilities including to many clinics that compete with Fresenius facilities, including but not limited to DaVita Dialysis Centers, Dialysis Clinics Inc. (DCI), and Renal Ventures Management LLC, among others.

102. When introduced into the body, the acetate contained in acid concentrates is converted into bicarbonates by the liver, which increases bicarbonate levels in the blood.

103. NaturaLyte and/or GranuFlo are dry powders.

104. The purported advantage of NaturaLyte and/or GranuFlo is to allow dialysis clinics to mix their own acid concentrate (with water at the clinics) so that Defendants did not have to ship liquid acid concentrate in large 55 gallon drums around the world, which had become expensive. Thus NaturaLyte and/or GranuFlo was designed, in part, to save costs since only the dry acid concentrate was being shipped.

105. All acid concentrates (liquid or dry) contain acid. Liquid products contain acetate, whereas NaturaLyte and/or GranuFlo contain sodium diacetate.

106. During dialysis, one of the goals is to reestablish the patient's proper electrolyte balance. Patients in renal failure tend to become acidotic, and that problem is corrected primarily by adding bicarbonate to their blood. Therefore, all dialysate solutions contain bicarbonate to correct the naturally occurring acidosis in patients in renal failure.

107. NaturaLyte and/or GranuFlo contain sodium diacetate (two acetates), whereas other products contain only acetic acid with one acetate. Once in the body, acetate is converted by the patient's liver into bicarbonate. Because NaturaLyte and/or GranuFlo results in two acetate molecules, conversion by the liver results in *two molecules of bicarbonate*. Thus, the net effect of using a dialysate that contains diacetate is that the patient is exposed to an unanticipated amount of bicarbonate and consequently an unanticipated amount of total buffer that exceeds what was intended and ordered by the physician attending to the patient. The conversion of diacetate in the liver to two molecules of bicarbonate results in a higher total buffer than ordered by the physician.

108. Bicarbonate levels are described in terms of milliequivalents per liter (mEq/L). When GranuFlo and/or NaturaLyte is used, it adds 8 mEq/L to the total amount of buffer (bicarbonate) delivered to the patient in comparison to other dialysates which do not exceed 4 mEq/L. In 2005, Fresenius estimated that, "for every 4 meq/L increase in the dialysate total buffer there will be a corresponding 1 – 2 meq/L change in the pre dialysis serum bicarbonate".

109. The net effect of administering GranuFlo and/or NaturaLyte to patients is that because of the sodium diacetate formulation, a significant number of dialysis patients develop unexpectedly elevated levels of bicarbonate in their blood. Patients with elevated bicarbonate

levels in their blood suffer from metabolic alkalosis, the opposite of acidosis, and high bicarbonate levels in the blood increases a patient's risk of cardiopulmonary arrest ("CP") or sudden cardiac arrest.

110. "Total buffer" includes both bicarbonate from bicarbonate dialysate and bicarbonate resulting from the metabolism of the two acetate molecules, resulting from the dissociation of sodium diacetate, contained in the acid dialysate., i.e., GranuFlo Dry Acid Concentrate and/or NaturaLyte Dry Acid Concentrate. If for example there are 33 mEq/L from the bicarbonate concentrate, which is delivered in the dialysate in conjunction with the acetate, and 4 mEq/L of acetate from the acid concentrate, the total buffer level is 37 mEq/L. However, where NaturaLyte and/or GranuFlo (a dry acid concentrate) is used, and there are 33 mEq/L from the bicarbonate concentrate, because NaturaLyte and/or GranuFlo contains diacetate and not acetate, the contribution to the total buffer from the acid concentrate will be 8 m Eq/L. In such cases, the total buffer would be 41 mEq/L and not 37 mEq/L as with acetate instead of diacetate.

111. At all relevant times of this lawsuit, Defendants knew, or should have known, that the concentration of acetic acid or sodium diacetate (acetic acid plus acetate) contained in NaturaLyte and/or GranuFlo, respectively, was leading to a dangerous increase in serum bicarbonate levels in patients undergoing hemodialysis. Defendants knew, or should have known, that this contributes to metabolic alkalosis, which is a significant risk factor associated with many health problems including heart arrhythmia, cardiopulmonary arrest and sudden cardiac death.

112. Defendants have been aware for years that disparities between the prescribed dialysate bicarbonate levels, total buffer levels, and bicarbonate settings and readings on the dialysis machines have been a long-term problem in dialysis care.

113. Defendants have been aware for years that the warnings, training and instructions related to NaturaLyte and/or GranuFlo were inadequate and non-existent. Defendants have also been aware for years that changing the design of the products was possible and would have easily avoided the dangers relating to the disparities between the prescribed dialysate bicarbonate levels, total buffer levels, and bicarbonate settings and readings on the dialysis machines.

114. Through information and belief, the NaturaLyte and/or Granuflo product line saw steadily increased market share since its introduction, and as of 2012 was used by the majority of nearly 400,000 hemodialysis patients in the U.S.

C. INCREASED BICARBONATE LEVELS CAN ADVERSELY AFFECT THE HEART

115. The heart is a four chambered muscle that must beat rhythmically and regularly to pump blood throughout the body. The rhythmic beating is controlled by an electrical circuit within the heart.

116. The electrical conduction of the heart is affected by many of the electrolytes that are adjusted during dialysis. The most commonly recognized of these electrolytes is potassium.

117. Sudden cardiac arrest or cardiopulmonary arrest occurs when the rhythmic beating of the heart becomes irregular so that the heart can no longer pump blood effectively. The most commonly referenced irregular heart beat that leads to sudden death is v-fib (ventricular fibrillation). This occurs when the ventricles of the heart simply quiver instead of actually contract or beat. The quivering ventricles do not pump blood, and if not corrected within minutes, the patient will die.

118. The human body has an elaborate mechanism to maintain its blood pH and its bicarbonate levels within a very narrow range. Patients with renal failure become acidotic (low

blood pH) and need to have their acidosis corrected by the addition of bicarbonate, which is always done during dialysis.

119. If the patient receives too much bicarbonate, he or she can be pushed outside the normal or tolerated range and become alkalotic (high blood pH). An elevated blood bicarbonate level is not something that commonly occurs in patients who are not on dialysis because the kidneys are very efficient at controlling the amount of bicarbonate in the blood.

120. When patients receive too much bicarbonate, as can occur with the use of NaturaLyte and/or Granuflo as alleged *supra*, an electrolyte imbalance can occur. Among other physiological changes, a patient's potassium and calcium may shift on a cellular level, resulting in a significant increase in the potential for an arrhythmia or fibrillation.

121. The manufacturer of a product used in hemodialysis, such as an acid concentrate, has a duty to advise and/or warn prescribing physicians and/or healthcare facilities of any and all risks, concerns, defects and other safety information regarding said product and its use.

D. FDA APPROVAL OF GRANUFLO

122. On or about July 17, 1991, FDA cleared K911459, GranuLyte via the 510(k) process upon Defendants statements that GranuLyte was substantially equivalent to a predicate product.

123. The purpose of a 510(k) submission is to demonstrate that a device is "substantially equivalent" to a predicate device (one that has been cleared by the FDA or marketed before 1976).

124. Human studies are not required for 510(k) clearance. FDA needs only to see that the product at issue in the 510(k) submission is substantially similar to a product already on the market either through FDA approval or clearance.

125. In other words a 510(k) process allows manufacturers to piggyback off a predicate device to demonstrate safety by showing their device is substantively equivalent to those predicate devices for which safety has already been established.

126. The FDA does not "approve" 510(k) submissions. It "clears" them as substantially equivalent if they have the same intended use as predicate devices. In other words, devices that do not have the same intended use cannot be substantially equivalent.

127. The FDA does not conduct product testing relating to safety or efficacy of any product. FDA relies and mandates that manufacturers do the proper testing to assure both safety and efficacy.

128. Marketing of a cleared device cannot begin until the company receives a clearance letter from the FDA.

129. It is not legal to advertise a 510(k) cleared device as "FDA-approved."

130. The predicate product Fresenius relied upon for substantial equivalence with respect to GranuLyte was Renal Systems Renapak Concentrate Mixing System, K840182.

131. Renal Systems Renapak Concentrate Mixing System had received clearance through the 510(k) process in or about 1984. The FDA reference number is K840182.

132. Renal Systems Renapak Concentrate Mixing System, K840182 was a dry dialystate concentrate mixing system.

133. Renal Systems Renapak Concentrate Mixing System, K840182, was cleared based upon the company's assurance that its product was substantially equivalent to a liquid dialysate product.

134. Renal Systems Renapak Concentrate Mixing System, K840182 included a dry acid concentrate made up of sodium acetate.

135. The predicate product that Defendants claimed its GranuLyte powder concentrations to be similar to was Renal Systems Renapak Concentrate Mixing System, also a dry powder concentrate.

136. Defendants' GranuLyte product that was the subject of the K911459, 1991 clearance, the same applications that Defendants claimed to be substantially equivalent to the Renal Systems Renapak Concentrate Mixing System containing sodium acetate, actually contained Sodium Diacetate in its dry acid concentrate.

137. Defendants recognized that the acid component was different, but also represented in a memorandum to FDA dated February 6, 1991 that, ". . .the use of sodium diacetate or acetic acid will have no effect on the final content of the solution. One would not be able to tell, in fact, whether acetic acid or sodium diacetate had been used."

138. Upon information and belief, Defendants did not conduct any safety studies on the change from acetate to diacetate in its acid concentrate.

139. Defenants' GranuLyte K911459 cleared in 1991, contained 4.0 mEq/L of sodium diacetate in its acid concentrate. When properly mixed with the bicarbonate concentration, the final dialysate contained 10.4 Gm/L of acid.

140. Upon information and belief, this is the first time sodium diacetate was used in hemodialysis.

141. In April 1992, Defendants submitted a premarket notification of their intent to market GranuLyte Dialysate Concentrate (a granulated formula) to the FDA. The April 1992 submission was made pursuant to a 510(k) application.

142. This submission is FDA reference number K22005.

143. GranuLyte that was the subject of the April 1992 510(k), K22005, contained 14.9

Gm/L of sodium diacetate, an increase of sodium diacetate from the amount approved by FDA in 1991. The FDA eventually cleared Granulyte in a granulated (dry) formula on March 30, 1994. The FDA's decision, in part, was based on the claim by Fresenius that the product was substantially equivalent to the dialysate products already on the market, specifically K911459 containing 10.4 Gm/L of sodium diacetate. In additional support for increasing the amount of sodium diacetate in its product, Fresenius' application relied upon a list of three other manufacturers' approved products, represented by Fresenius only as being "similar" to GranuLyte, which upon information and belief, included sodium acetate, NOT sodium diacetate.

144. Later that year, on or about September 8, 1992, Fresenius changed the trade-name from GranuLyte to GranuFlo.

145. Upon information and belief, by no later than 1997, GranuFlo contained 8 mEq/L of sodium diacetate. According to the publicly available information at FDA, Fresenius did not submit a 510(k) application to allow for this increase in sodium diacetate.

146. On or about August, 2002, Defendants again submitted a 510(k) submission to alter GranuFlo.

147. Fresenius again submitted a 510(k) submission for the "Fresenius Naturalyte Granuflo Dry Acid Concentrate"[1]

148. This submission is referenced by K030497.

149. Fresenius stated in its summary that "The Fresenius Naturalyte Granuflo Dry Acid Concentrate is designed to be used as direct product replacement for the current Granuflo Concentrate (Series 1000, 2400 and 3000)."

150. Fresenius also assured the FDA that "the new Fresenius Naturalyte Granuflo Dry Acid Concentrate has the same chemical composition as the predicate devices." Those predicate

[1] *See* Fresenius 510(k) submission, K030497.

devices identified were K911459, when Fresenius first began using sodium diacetate in 1991, and K922055 when Fresenius increased the amount of sodium diacetate in its concentrates in 1994.

151. It was not until on or about January 14, 2003, that FDA eventually cleared Fresenius' 510(k) submission.

E. DEFENDANTS KNEW THERE WERE PROBLEMS WITH BICARBONATE LEVELS

152. Fresenius understood by March 23, 2001 that "total buffer" was an issue that was being confused at the clinic level. Fresenius understood that clinics seemed to be confused with the bicarbonate delivery during dialysis.

153. On or about this date, Fresenius Medical Officer Michael Lazarus, M.D. told Fresenius medical directors that "[t]here is apparently confusion regarding bicarbonate delivery and the labeling on bicarbonate and acid concentrate products."

154. In that same memo, Dr. Lazarus explained that dialysis machines must be calibrated differently depending upon the acid concentrate used and stated "When GranuFlo is used, an advantage accrues in that there is a greater amount of acetate available to be metabolically converted to bicarbonate in the body." Dr. Lazarus stressed, "[T]he total buffer is the sum of the acetate and bicarbonate."

155. Dr. Lazarus concluded the memo by telling Fresenius medical directors that they "must" observe and monitor the patient's serum bicarbonate level to determine that the prescribed dialysate bicarbonate is actually being delivered and is appropriate for the patient considering the "total buffer."

156. Defendants did not communicate this information to non-Fresenius entities.

157. In or about 2004, Defendants conducted a retrospective study of dialysis patients

who had converted from previously approved acid concentrates to GranuFlo containing diacetate between August 2002 and April 2003 ("2004 Retrospective Study").

158. Upon information and belief, the goal of Defendants' 2004 Retrospective Study was to determine the efficacy of acid concentrate containing diacetate (*i.e.*, GranuFlo) in improving pre-dialysis bicarbonate levels and/or reducing metabolic acidosis when compared with a standard acid concentrate.

159. In or about 2004, Defendants evaluated the results of their 2004 Retrospective Study, which revealed:

a. higher than normal pre-dialysis bicarbonate levels as a result of the administration of GranuFlo containing diacetate;

b. higher than normal post-dialysis bicarbonate levels as a result of the administration of GranuFlo containing diacetate; and

c. an increase in cases of metabolic alkalosis as a result of the administration of GranuFlo containing diacetate.

160. As a result of their 2004 Retrospective Study, Defendants were on notice and/or should have been on notice of the foregoing.

161. Defendants did not communicate this information to non-Fresenius entities or with the FDA.

162. Upon information and belief, despite the results of their 2004 Retrospective Study and their knowledge of the severe health risks associated with NaturaLyte and/or GranuFlo, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo from the FDA, the medical community, the Plaintiffs, the Plaintiffs' treating physicians and/or healthcare providers and the public.

163. Upon information and belief, despite the results of their 2004 Retrospective Study

and their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo, Defendants failed to advise and/or warn all doctors and/or other healthcare providers treating patients with NaturaLyte and/or GranuFlo to reduce the amount of bicarbonates being administered to and/or received by the patient during dialysis to take into account the additional bicarbonates that these individuals were receiving from NaturaLyte and/or GranuFlo.

164. In or about 2003, at or about the same time the 2004 Retrospective Study was being conducted, Defendants conducted a mortality study of hemodialysis patients ("Defendants' 2003 Mortality Study").

165. The data and/or information underlying Defendants' 2003 Mortality Study as well as the exact results remain in the custody and/or possession of Defendants.

166. Upon information and belief, Defendants evaluation of the results of their 2003 Mortality Study revealed an increase in death risk for patients whose pre-dialysis serum bicarbonate levels were at or above 24 mEq/L.

167. Upon information and belief, Defendants evaluation of the results of their 2003 Morality Study revealed a 20% increase in death risk for patients whose pre-dialysis serum bicarbonate levels were at or above 28 mEq/L.

168. As a result of Defendants' 2003 Mortality Study and 2004 Retrospective Study, Defendants were on notice and/or should have been on notice that the administration of NaturaLyte and/or GranuFlo containing diacetate resulted in a significant increase in serum bicarbonate levels, which in turn resulted in an increase in death risk for patients receiving NaturaLyte and/or GranuFlo.

169. As a result of Defendants' 2003 Mortality Study and 2004 Retrospective Study,

Defendants were on notice and/or should have been on notice that the design of NaturaLyte and/or GranuFlo was defective.

170. Defendants were on notice and/or should have been on notice of their obligation to report the results of their 2003 Mortality Study and 2004 Retrospective Study to the medical community, the Plaintiffs, the Plaintiffs' treating physicians, the Plaintiffs' healthcare providers, the FDA and/or the public.

171. Upon information and belief, despite the results of their 2003 Mortality Study and 2004 Retrospective Study and their knowledge of the defectiveness and/or severe health risks associated with NaturaLyte and/or GranfuFlo, Defendants intentionally and willfully concealed their knowledge of these results and/or the increased severe health risks associated with NaturaLyte and/or GranuFlo from the FDA, the medical community, the Plaintiffs, the Plaintiffs' treating physicians and healthcare providers and the public.

172. Upon information and belief, despite the negative safety results of their 2003 Mortality Study and/or 2004 Retrospective Study, Defendants affirmatively misrepresented that NaturaLyte and/or GranuFlo was more effective and safer than other acid concentrates on the market.

173. Defendants advertised and/or marketed that the use of NaturaLyte and/or GranuFlo resulted in a 33% reduction in the prevalence of acidosis, without any timely and adequate disclosure of the deleterious effects of alkalosis.

174. Based upon the results of their 2004 Retrospective Study, at all relevant times, Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market to prevent and/or treat metabolic acidosis.

175. Based upon the results of their 2004 Retrospective Study, at all relevant times,

Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market to increase pre-dialysis serum levels to greater than 20 mEq/L.

176. Based upon the results of their 2004 Retrospective Study, at all relevant times, Defendants advised doctors, dialysis clinics and/or healthcare providers to use NaturaLyte and/or GranuFlo over other acid concentrate on the market and did not counsel doctors, dialysis clinics and/or healthcare providers to pay attention to the increase in serum bicarbonate levels as a result of the use of NaturaLyte and/or GranuFlo.

177. In October, 2004, The Dialysis Outcomes and Practice Patterns Study ("DOPPS") was published in the American Journal of Kidney Diseases.

178. The authors concluded that there is a significantly increased risk for mortality for patients with a very high pre-dialysis serum bicarbonate level (>27 mEq/L). The authors suggested that mild pre-dialysis acidosis may be beneficial. They stressed the need for evaluation and correction of both pre-dialysis severe acidosis and alkalosis. (<18 mEq/L or >27 mEq/L).

179. Defendants knew or should have known that high serum bicarbonate levels increases the patients' risk of mortality. Defendants knew or should have known by October, 2004 that alkalosis pre-dialysis can be just as dangerous and/or more dangerous than mild acidosis.

180. Defendants knew or should have known by July 5, 2005 that the mean bicarbonate levels in patients who were being administered NaturaLyte and/or Granuflo, were rising and that in fact some patients were actually alkalotic pre-dialysis instead of acidotic. Defendants knew or should have known that there was still confusion in the clinics about the

added bicarbonate delivered by NaturaLyte and/or GranuFlo.

181. In an internal company memorandum, dated on or about July 5, 2005, Defendants' Chief Medical Officer informed Defendants' medical directors that in just a few years of using GranuFlo in Defendants' own clinics, the mean bicarbonate for Fresenius patients had risen from 20 mmol/L to 24 mmol/L.

182. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors of the fact that some patients are actually now alkalotic pre-dialysis.

183. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors that mortality increases when the serum bicarbonate levels are >28. Defendants' Chief Medical Officer communicated to the Defendants' medical directors that GranuFlo delivers an additional 4 mEq/L of sodium acetate (total 8 mEq/L). "The acetate concentration in GranuFlo is double that of traditional liquid acid concentrates."

184. In that same July 5, 2005 memorandum, Defendants' Chief Medical Officer communicated to the Defendants' medical directors that it is important to understand and prescribe the proper bicarbonate concentration to deliver the desired total buffer.

185. Defendants did not communicate the information contained in the July 5, 2005 internal memo to non-Fresenius entities or with the FDA.

186. By April, 2009, Defendants knew or should have known that there was still a problem in the clinics with pre-dialysis bicarbonate levels of the patients and the delivery of NaturaLyte and/or GranuFlo.

187. In an internal memo, dated April 13, 2009, "Dialysate Concentrate Change and

Bicarbonate/Buffer," Drs. Lazarus and Hakim, the Medical Officers for Fresenius tell the Fresenius Medical Directors that there still seems to be confusion about bicarbonate settings and prescriptions for bicarbonate. Drs. Lazarus and Hakim explain that the bicarbonate setting on the machines represents only the bicarbonate level in the dialysate. "This number does **NOT** include the 4 mEq/L of acetate delivered by the liquid acid solution or the 8 mEq/L of acetate delivered by the GranuFlo acid powder."

188. In that same April 13, 2009 memorandum, Drs. Lazarus and Hakim recommend that patients have a dialysis prescription that maintains the patient with a pre-dialysis serum bicarbonate in the range of 20-23 mEq/L. They also reference "several in-depth discussions" of the bicarbonate delivery available for review, (Dec. 7, 2000, March 21, 2001, and July 5, 2007), and "encouraged" the directors or nursing staff to review them all.

189. Defendants did not communicate the information contained in the April 13, 2009 memo to non-Fresenius entities or with the FDA.

190. In April 2009, a conference of nephrologists and dialysis practitioners and providers was held in Boston, Massachusetts. Its title was: "ESRD: State of the Art and Charting the Challenges for the Future." It was attended by Fresenius employees, including Raymond Hakim, M.D., Ph.D., who at the time was Chief Medical Officer for Fresenius Medical Care. Dr. Hakim served on the Steering Committee for the conference.

191. During the conference, cardiopulmonary arrest was noted to be the number 1 ranking cause of death for dialysis patients, accounting for 59% of cardiovascular-related deaths among dialysis patients. It was concluded that cardiovascular-related deaths were caused by uremic cardiomyopathy, characterized by left ventricular hypertrophy (LVH), LV dysfunction, and LV dilatation, and not due to atherosclerotic heart disease.

192. Sometime in 2009 or 2010, Fresenius revised the manual used by operators for certain Fresenius-manufactured dialysis machines, including the 2008T model. The revisions instructed users, "*When entering the Acetate value for GranuFlo concentrate, only half of the listed value on the label should be entered. For example, if the label shows an Acetate value of 8, then only enter 4.*" (2008T Machine Operator's Manual P/N 490122 Rev E Copyright 2008-2010).

193. From 2008 through 2010 Fresenius failed to provide notification to all users of NaturaLyte and/or GranuFlo, of the necessity to "halve" Acetate levels when setting the parameters on dialysis machines while using these products. To the extent Fresenius provided information, it did so partially, selectively and haphazardly in a way calculated to avoid general dissemination of necessary warnings, instructions and problems associated with its products. Fresenius' failure to fully and forthrightly inform and warn the medical/dialysis community directly affected patient health and safety and led to the deaths of innumerable patients.

194. Sometime after the Boston Conference, Dr. Hakim undertook a study of patients who suffered cardiopulmonary arrest and sudden cardiac death in Fresenius clinics during 2010, which it first reported in an Internal Memorandum to Fresenius Clinic Medical Directors on November 4, 2011.

195. In an internal memorandum dated November 4, 2011, the Fresenius Medical Office reports Dr. Hakim's findings of his case-control study of 941 patient deaths in 667 Fresenius clinics. Fresenius tells the Fresenius medical directors that alkalosis is a significant risk factor associated with cardiopulmonary arrest. "The major cause of metabolic alkalosis in dialysis patients is inappropriately high dialysate total buffer concentration." He reports:

a. Over time, there has been increasing serum bicarbonate levels pre-dialysis. "This issue needs to be addressed urgently."

b. Unadjusted OR=8.3 for cardiac event in patients pre-dialysis serum level >28 mEq/L. adjusted 6.3.

c. Again states that GranuFlo delivers more acetate and thus more bicarb than other formulas.

196. The internal November 4, 2011 memorandum went on to further state in its "summary of findings" that: "The current analysis determined that: "*borderline elevated pre-dialysis bicarbonate levels and over alkalosis are significantly associated with 6 to 8 fold greater increase of cardiopulmonary arrest and sudden cardiac death in the dialysis facility.*" (italics in original)..."In light of these troubling findings, we strongly recommend that physicians adjust dialysate bicarbonate prescriptions monthly for individual patients, with immediate attention to patients with serum pre-dialysis bicarbonate level of >24 mEq/L." The memo further urges that this dangerous issue "needs to be addressed urgently."

197. Despite Defendants' knowledge of this significant patient safety risk, Fresenius willfully and knowingly failed to notify, warn and/or instruct non-Fresenius dialysis clinics and operators to whom Fresenius sold and marketed NaturaLyte and/or GranuFlo, nor did the company inform patients or the FDA of the results of this study. Only after the November 4, 2011 Internal Memo was anonymously leaked to the FDA, which led to questioning of Fresenius in late March 2012, did Fresenius send any informational correspondence to dialysis facilities using its products. Much of the detail contained in the Internal Memo, however, was absent in the "Urgent Product Notifications" sent out by Fresenius.

F. GRANUFLO AND NATURALYTE BECOME THE SUBJECT OF A CLASS I RECALL

198. On or about March 2, 2012, FDA received an anonymous complaint raising concerns over the elevated bicarbonate levels and dialysate concentrate dose error. FDA also received the November 4, 2011 memo.

199. Shortly thereafter, in March 2012, Defendant Fresenius Medical Care North America received an inquiry from the FDA specifically about GranuFlo and NaturaLyte and alkalosis.

200. It was only on March 29, 2012, after the FDA became aware of the dangers posed by GranuFlo and the number of instances of CP in dialysis patients treated by that product, that Fresenius sent a notice to non-Fresenius clinics purchasing and using GranuFlo stating that "NaturaLyte Liquid contains 4.0 mEq/L of acetate and GranuFlo contributes 8.0 mEq/L of acetate to the final dialysate; which in addition to bicarbonate, combine to the total buffer that the patient receives from the dialysate. Since acetate is rapidly converted into bicarbonate by the liver, the bicarbonate prescription entered into the dialysis machine underestimates the total buffer that the patient receives from the dialysate by ~8 mEq/L with dialysate prepared from GranuFlo (powder) or by ~4 m.Eq/L with dialysate prepared from NaturaLyte (liquid)." This correspondence did not mention any patient blood levels and failed to discuss in any manner the most at-risk population of all, "acute" dialysis patients.

201. The March 29, 2012 notice further stated that "[r]ecent analyses performed by FMCNA [Fresenius Medical Care North America] hemodialysis (HD) patient safety data confirms that alkalosis [high levels of bicarbonate] is a significant risk factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of and additive to the risk of CP arrest associated with pre-dialysis hypokalemia. A major cause of metabolic alkalosis in dialysis patients is inappropriate high dialysate total buffer concentration."

202. The March 29, 2012 notice contained an "urgent product notification involving the NaturaLyte and GranuFlo powder product lines" and recommended that "clinicians exercise their best judgment regarding bicarbonate and total buffer base prescriptions for each patient."

203. GranuFlo and/or NaturaLyte are defective and unreasonably dangerous for their intended use because they create an unreasonably dangerous level of bicarbonate in the blood stream during dialysis causing metabolic alkalosis and a corresponding substantial increase in the risk of cardiopulmonary arrest during dialysis treatment. Further, there was no warning or instructions about this risk.

204. Fresenius dialysis machines are defective and unreasonably dangerous due to inadequate instructions and warnings when used with NaturaLyte and/or GranuFlo, in that the operator must "halve" the acetate level to account for the dangers inherent in Fresenius concentrated dialysates but the requirement to "halve" the acetate levels was not described, warned about, or instructed about.

205. Fresenius failed to properly warn of the dangers associated with the use of its products up to March 29, 2012, when it manufactured and distributed it products without proper warnings and instructions, and attempted to conceal those dangers from the public and the FDA up to and including March 29, 2012. All the while being in possession of information relating to the risks posed by its products, Fresenius nevertheless continued to manufacture and distribute its products ignoring the information it possessed and failing to warn and instruct clinics, doctors, patients and others involved in the administration of dialysis using Fresenius' products.

206. On March 29, 2012, the FDA reported Fresenius's voluntary Class 1 recall of GranuFlo Acid Concentrate and NaturaLyte Liquid. This recall in effect warned users of the heightened risk for low blood pressure, hypokalemia (low potassium levels), hypoxemia (low blood oxygen), hypercapnia (high carbon dioxide levels), and cardiac arrhythmia, possibly leading to sudden death associated with the products.

207. On a teleconference between the FDA and Fresenius Medical Care North America on April 27, 2012, Fresenius was asked to provide modifications to their product labels to reflect appropriate warnings regarding total buffer.

208. The New York Times reported on June 14, 2012, that the Food and Drug Administration was investigating whether the nation's largest operator of dialysis centers violated federal regulations by failing to inform customers of a potentially lethal risk connected to one of its products.

209. The article quoted an FDA official:

> "Personally, I'm troubled by the fact that Fresenius on its own initiative didn't notify its entire customer base of this particular concern," Steven Silverman, director of compliance for the F.D.A.'s medical devices division, said in an interview this week.
>
> Mr. Silverman said the agency could issue a warning letter to Fresenius if it determined the company should have reported the safety concerns. But even if the company had no legal obligation, he said, "Candidly, I just think it's bad business and not in the interest of the public health to sit on information about risks."

210. The article also quoted:

> Dr. Thomas F. Parker III, chief medical officer at Renal Ventures, a dialysis chain that used Fresenius products, agreed. "If the data was sufficient to warn their doctors, then all users of the product should have been made aware of it."

211. On June 22, 2012, the FDA sent a letter to the Chairman/CEO of Fresenius Medical Care North America. In the letter, the FDA concluded that there is a reasonable probability that the use of, or exposure to, NaturaLyte and GranuFlo will cause serious adverse health consequences, including death. Accordingly, the FDA classified it as a Class I recall. The FDA explained that the seriousness of this recall requires 100 percent effectiveness checks and

there must be verification that every consignee has been notified of the recall and appropriate action has been taken.

212. Class I recalls are the most serious recalls. These recalls are for dangerous or defective products that predictably could cause serious health problems or death.

213. When explaining the recall of GranuFlo and NaturaLyte that was initiated March 29, 2012, the FDA explained that "the manufacturer is cautioning clinicians to be aware of the concentration of acetate or sodium diacetate (acetic acid plus acetate) contained in Fresenius' NaturaLyte Liquid and GranuFlo Dry Acid Concentrate. Inappropriate prescription of these products can lead to a high serum bicarbonate level in patients undergoing hemodialysis. This may contribute to metabolic alkalosis, which is a significant risk factor associated with low blood pressure, hypokalemia, hypoxemia, hypercapnia and cardiac arrhythmia, which, if not appropriately treated, may culminate in cardiopulmonary arrest. This product may cause serious adverse health consequences, including death."

G. DEFENDANTS FAILED TO DISCLOSE THAT NATURALYTE AND/OR GRANUFLO ARE DEFECTIVE – RESULTING IN INJURY AND DAMAGES TO PLAINTIFFS

214. On or about November 16, 2011, Dr. Raymond Hakim resigned from Fresenius. Through information and belief, at all relevant times to this lawsuit there was collusion involving Defendants and individuals in several of Defendants' departments and organizations to hide, mislead, and obscure information about the extreme patient safety hazard associated with the use of GranuFlo and/or NaturaLyte in order to maintain their market share as well as to minimize and diffuse the legal risks for Defendants.

215. As early as 2005 if not earlier, Defendants had knowledge of the risks associated with NaturaLyte and/or GranuFlo but Defendants failed to adequately and lawfully warn

consumers, like Plaintiffs, their physicians and healthcare providers and the medical community of the risks despite Defendants' knowledge as of about that time or earlier.

216. Plaintiffs and their health care providers relied upon the misrepresentations and actions of Defendants insofar as the hemodialysis products provided were safe and effective for use as labeled during hemodialysis.

217. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have suffered death, serious permanent physical injury, life-changing, life-altering pain and suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital, surgical and funeral expenses and other expenses related to diagnosis and treatment thereof, for which Defendants are liable. As a direct and proximate result of Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have suffered and will continue to suffer pecuniary and other losses for which Defendants are liable.

218. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo and their resulting injuries, Plaintiffs have suffered damages and harm, including but not limited to, emotional distress for which Defendants are liable. Plaintiffs have incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort for which Defendants are liable.

219. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental

anguish, and have been deprived of their ordinary pursuits and enjoyments of life for which Defendants are liable.

220. As a direct and proximate result of the acts and omissions of Defendants, and Plaintiffs' use of NaturaLyte and/or GranuFlo, Plaintiffs' spouses have lost, presently and in the future, their spouse's companionship, services, society and the ability of Plaintiffs' spouses in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs' spouses have been caused mental anguish and suffering spouses in said respect has been impaired and depreciated, and the marital association between husband and wife has been altered, and as such, the Plaintiffs' spouses have been caused mental anguish and suffering for which Defendants are liable.

221. Plaintiffs' serious injuries and or death as a result of their exposure to NaturaLyte and/or GranuFlo, was caused by and was the direct and proximate result of Defendants' breaches of warranty and/or the negligence or other wrongful conduct of Defendants by and through its agents, servants, workmen and employees, in any or all of the following respects:

a. in failing to properly design, manufacture and test NaturaLyte and/or GranuFlo;

b. in selling, marketing and distributing NaturaLyte and/or GranuFlo in a dangerously defective condition;

c. in selling, marketing and distributing NaturaLyte and/or GranuFlo when it was not reasonably fit and suitable for its ordinary and intended purpose;

d. in failing to warn purchasers and users of NaturaLyte and/or GranuFlo's defective condition before, during and after sale and delivery of the product;

e. in failing to properly inspect and test NaturaLyte and/or GranuFlo;

f. in selling, marketing and distributing NaturaLyte and/or GranuFlo when it knew or should have known of its inherent design defects;

g. in failing to properly and fully investigate prior incidents involving deaths and other personal injuries related to the use of NaturaLyte and/or GranuFlo during dialysis;

h. in failing to correct known design and engineering deficiencies; and,

i. in failing to properly or adequately address defects in NaturaLyte and/or GranuFlo and implementing an inadequate Recall Campaign that defendants knew or should have known was deficient and not likely to correct the defects and dangers inherent in NaturaLyte and/or GranuFlo.

222. Defendants' failure to disclose the defective nature of NaturaLyte and/or GranuFlo, the limited reach of its recall campaign, and the failure to notify the families of patients who suffered serious injury and/or death during dialysis, of the association between NaturaLyte and/or GranuFlo and these injuries prevented Plaintiffs from knowing their injuries were potentially related to the use of the defective NaturaLyte and/or GranuFlo product.

H. DISCOVERY RULE AND TOLLING

223. Plaintiffs assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

224. Where applicable, the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

225. Despite diligent investigation by Plaintiffs into the cause of their injuries the nature of Plaintiffs' injuries and damages, and their relationship to NaturaLyte and/or GranuFlo was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

Therefore, under appropriate application of the discovery rule, Plaintiffs' suit was filed well within the applicable statutory limitations period.

226. The running of the statute of limitations in this cause should also be tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiffs and/or Plaintiffs' physicians of the true risks associated with the Products. As a result of the Defendants' fraudulent concealment, Plaintiffs and/or Plaintiffs' physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

I. FRESENIUS MEDICAL CARE HOLDINGS, INC. WAS UNDER A HEIGHTENED DUTY TO REPORT THE HEALTH PROBLEMS ASSOCIATED WITH GRANUFLO AND NATURALYTE

227. On or about January 19, 2000, Defendant Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America and certain of its subsidiaries agreed to pay the United States $486 million to resolve a sweeping investigation of health care fraud at National Medical Care, Inc. ("NMC"), Fresenius' kidney dialysis subsidiary. Pursuant to the agreement, three NMC subsidiaries pled guilty to three separate conspiracies and to pay a record setting $101 million in criminal fines. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America agreed to pay a record setting $385 million to resolve related civil False Claim Act claims.

228. The above settlement by Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America and its subsidiaries involved allegations that Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America's subsidiaries submitted false

claims for reimbursement through Medicare and that these same subsidiaries provided payments, discounts and other inducements to dialysis facilities to obtain their blood testing business in violation of the Medicare Anti-Kickback Act.

229. In addition to the payment of $486 million to settle the healthcare fraud claims, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America also entered into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the Department of Health and Human Services on January 18, 2000. The CIA requires Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to take actions to prevent misconduct in the future. Among other things, the CIA, which had an 8 year term, required Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to maintain a Corporate Integrity Program which included corporate compliance officers at various levels of the organization, a confidential employee hotline for employees to report suspected misconduct, and a corporate training program on designated compliance issues. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America was also required to retain an Independent Review Organization, to conduct compliance audits, and to submit an annual report to the OIG relating to compliance efforts.

230. The CIA also imposed heightened reporting requirements upon Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America. Specifically, the CIA requires Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America to report "a violation of the obligation to provide items or services of a quality that meet professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care

program beneficiary or places the beneficiary unnecessarily in a high-risk situation. A Reportable Event may be the result of an isolated event or a series of occurrences."

231. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America violated the CIA by failing to report the health risks associated with GranuFlo and/or NaturaLyte. This failure to report the health risks associated with GranuFlo and/or NaturaLyte has resulted in injuries to the Plaintiffs in the instant litigation.

232. Additionally, on May 10, 2002, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America entered a similar settlement agreement with respect to healthcare fraud claims for individuals who were participating in clinical trials. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America paid $1,658,923 to resolve these claims.

233. Finally, on May 26, 2011, Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America entered a similar settlement agreement to resolve healthcare fraud claims with respect to unauthorized claims for renal care. Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America paid $82,642,592 to resolve these claims.

V. CLAIMS FOR RELIEF

COUNT I

STRICT LIABILITY

234. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

235. At the time of Plaintiffs' injuries, Defendants' NaturaLyte and/or GranuFlo was defective and unreasonably dangerous to foreseeable patients.

236. The NaturaLyte and/or GranuFlo used by Plaintiffs was in the same, or substantially similar, condition as it was when it left the possession of Defendants.

237. Plaintiffs did not misuse or materially alter the NaturaLyte and/or GranuFlo that they used.

238. Defendants are strictly liable for Plaintiffs' injuries in the following ways:

a. The NaturaLyte and/or GranuFlo, as designed, marketed, distributed, packaged, manufactured, sold and supplied by the Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to properly market, design, manufacture, distribute, supply, package and sell NaturaLyte and/or GranuFlo;

c. Defendants failed to warn and place adequate warnings and instructions on NaturaLyte and/or GranuFlo;

d. Defendants failed to adequately test NaturaLyte and/or GranuFlo;

e. Defendants failed to provide timely and adequate warnings and instructions after they knew of the risk of injury associated with the use of NaturaLyte and/or GranuFlo prior to the injuries to Plaintiffs; and,

f. Defendants failed to market a feasible alternative design for the subject NaturaLyte and/or GranuFlo that would have prevented Plaintiffs' injuries.

239. Defendants' actions and omissions were the direct and proximate cause of Plaintiffs' injuries.

240. Defendants' conduct, as described above, was extreme and outrageous.

241. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT II

NEGLIGENT FAILURE TO WARN

242. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

243. Before Plaintiffs used NaturaLyte and/or GranuFlo, and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants knew or had reason to know that NaturaLyte and/or GranuFlo was dangerous and created an unreasonable risk of bodily harm to patients.

244. Defendants had a duty to exercise reasonable care to warn patients, including Plaintiffs, of the dangerous conditions and circumstances that could lead to serious injury or death from using NaturaLyte and/or GranuFlo.

245. Despite the fact that Defendants knew or had reason to know that NaturaLyte and/or GranuFlo was dangerous, Defendants failed to exercise reasonable care in warning the medical community and patients, including Plaintiffs, of the dangerous conditions, circumstances and facts that could lead to serious injury or death from using NaturaLyte and/or GranuFlo.

246. Plaintiffs' injuries were the direct and proximate result of Defendants' failure to warn of the dangers of NaturaLyte and/or GranuFlo.

247. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the

safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT III

NEGLIGENT DESIGN

248. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

249. Defendants are the manufacturers, sellers, distributors, marketers, and suppliers of NaturaLyte and/or GranuFlo which was negligently designed.

250. Defendants failed to exercise reasonable care in designing, developing, formulating, manufacturing, inspecting, testing, packaging, selling, distributing, labeling, marketing, and promoting NaturaLyte and/or GranuFlo which is defective and presented an unreasonable risk of harm to patients, including Plaintiffs.

251. As a result, NaturaLyte and/or GranuFlo contain defects in design, which renders it dangerous to patients, including Plaintiffs, when used as intended or as reasonably foreseeable to Defendants. The design defects render NaturaLyte and/or GranuFlo more dangerous than other dialysis chemicals and cause an unreasonable increased risk of injury, including but not limited to cardio pulmonary arrest, sudden cardiac death and other adverse events.

252. Plaintiffs used NaturaLyte and/or GranuFlo in a reasonably foreseeable manner, and substantially as intended by Defendants.

253. The subject NaturaLyte and/or GranuFlo was not materially altered or modified after manufacture by Defendants and before used by Plaintiffs.

254. The design defects directly rendered the subject NaturaLyte and/or GranuFlo defective and were the direct and proximate result of Defendants' negligence and failure to use reasonable care in designing, testing, and manufacturing NaturaLyte and/or GranuFlo.

255. As a direct and proximate result of Defendants' negligent design of NaturaLyte and/or GranuFlo, Plaintiffs suffered injuries.

256. Despite the fact that Defendants knew or should have known that NaturaLyte and/or GranuFlo was defectively designed, contained design defects, and caused an unreasonable risk of harm, Defendants designed, manufactured, sold, distributed, and marketed NaturaLyte and/or GranuFlo to patients, including the medical community and Plaintiffs, and failed to warn patients, the medical community, and Plaintiffs of the increased risk of harm relative to other dialysis chemicals.

257. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT IV

NEGLIGENCE

258. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury*

Demand in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

259. Defendants had a duty to exercise reasonable care in the manufacture, labeling, marketing, sale, packaging and distribution of NaturaLyte and/or GranuFlo including a duty to assure that it did not cause unreasonable, dangerous side-effects to users.

260. Defendants failed to exercise ordinary care in the manufacture, sale, warnings, quality assurance, quality control, packaging and distribution of NaturaLyte and/or GranuFlo in that Defendants knew or should have known that it created a high risk of unreasonable harm.

261. Defendants were negligent in the design, manufacture, advertising, warning, marketing, packaging and sale of NaturaLyte and/or GranuFlo in that, among other things, they:

a. Failed to use due care in designing and manufacturing NaturaLyte and/or GranuFlo so as to avoid the aforementioned risks to individuals;

b. Failed to accompany NaturaLyte and/or GranuFlo with proper and adequate warnings regarding all possible adverse side-effects associated with its use, dosing instructions and the comparative severity and duration of such adverse effects, including but not limited to serious cardio-pulmonary arrest, sudden cardiac death, and other adverse cardiac events. The warnings given did not accurately reflect the symptoms, scope or severity of the side effects;

c. Failed to provide adequate training and instruction to medical care providers for the appropriate use of NaturaLyte and/or GranuFlo;

d. Placed unsafe products into the stream of commerce; and,

e. Were otherwise careless or negligent.

262. Despite the fact that Defendants knew or should have known that NaturaLyte and/or GranuFlo caused unreasonable, dangerous side-effects which many users would be unable to remedy by any means, Defendants continued to market NaturaLyte and/or GranuFlo to patients, including the medical community and Plaintiffs.

263. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT V

NEGLIGENT MISREPRESENTATION

264. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

265. Prior to Plaintiffs' first dose of NaturaLyte and/or GranuFlo and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants misrepresented the degree to which NaturaLyte and/or GranuFlo was a safe and effective means for dialysis.

266. Defendants also failed to disclose material facts regarding the safety and efficacy of NaturaLyte and/or GranuFlo, including information regarding increased adverse events and harmful side-effects.

267. Defendants had a duty to provide Plaintiffs, physicians, and other patients with true and accurate information and warnings of any known risks and side-effects associated with the NaturaLyte and/or GranuFlo products they marketed, distributed and sold.

268. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with NaturaLyte

and/or GranuFlo that their representations regarding these drugs were false, and that they had a duty to disclose the dangers of NaturaLyte and/or GranuFlo.

269. Defendants made the representations, and otherwise failed to disclose material facts, concerning NaturaLyte and/or GranuFlo with the intent to induce patients, including Plaintiffs, to act in reliance thereon in receiving and/or using NaturaLyte and/or GranuFlo in dialysis treatment.

270. Plaintiffs justifiably relied on Defendants' representations and non-disclosures by choosing to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

271. Defendants' misrepresentations and omissions regarding the safety and efficacy of NaturaLyte and/or GranuFlo were the direct and proximate cause of Plaintiffs' injuries.

272. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VI

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

273. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

274. At the time Defendants marketed, distributed and sold NaturaLyte and/or GranuFlo to Plaintiffs, Defendants warranted that the NaturaLyte and/or GranuFlo was merchantable and fit for the ordinary purposes for which it was intended.

275. Patients, including Plaintiffs, were intended direct or third party beneficiaries of the warranty.

276. NaturaLyte and/or GranuFlo was not merchantable and fit for its ordinary purpose, because it had an unacceptable propensity to lead to the serious personal injuries described in this *Master Complaint and Jury Demand.*

277. Plaintiffs reasonably relied on Defendants' representations that NaturaLyte and/or GranuFlo was safe and free of defects.

278. Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of Plaintiffs' injuries.

279. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VII

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

280. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury*

Demand in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

281. Defendants manufactured, marketed, supplied and sold NaturaLyte and/or GranuFlo with an implied warranty that it was fit for the particular purpose of being a safe dialysis chemical.

282. Patients, including Plaintiffs, were the intended direct or third-party beneficiaries of the warranty.

283. NaturaLyte and/or GranuFlo was not fit for the particular purpose of being a safe dialysis chemical since it presents a serious risk of personal injury, which risk is much higher than other dialysis chemicals.

284. Plaintiffs reasonably relied on Defendants' representations that NaturaLyte and/or GranuFlo was safe and effective for dialysis.

285. Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of Plaintiffs' injuries.

286. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT VIII

BREACH OF EXPRESS WARRANTY

287. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

288. Defendants expressly warranted that NaturaLyte and/or GranuFlo were safe and effective to members of the consuming public, including Plaintiffs.

289. Members of the consuming public, including patients such as Plaintiffs, were intended direct or third-party beneficiaries of the warranty.

290. Defendants marketed, promoted, distributed and sold NaturaLyte and/or GranuFlo as a safe product.

291. NaturaLyte and/or GranuFlo do not conform to these express representations because it is not safe and has serious side-effects, including serious personal injuries and death.

292. Defendants breached their express warranty in one or more of the following ways:

a. NaturaLyte and/or GranuFlo as designed, manufactured, promoted, distributed, marketed, sold and/or supplied by the Defendants, was defectively designed and placed in to the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

b. Defendants failed to warn and/or place adequate warnings and instructions on NaturaLyte and/or GranuFlo;

c. Defendants failed to adequately test NaturaLyte and/or GranuFlo; and,

d. Defendants failed to provide timely and adequate post-marketing warnings and instructions after they knew the risk of injury from NaturaLyte and/or GranuFlo.

293. Plaintiffs reasonably relied upon Defendants' warranty that NaturaLyte and/or GranuFlo were safe and effective when they received and/or used NaturaLyte and/or GranuFlo in dialysis treatment.

294. Plaintiffs' injuries were the direct and proximate result of Defendants' breach of their express warranty.

295. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the patients and users of their products with knowledge of the safety problems and suppressed this knowledge from the general public through their marketing and advertising, as well as other means. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct, which was wanton and willful, warrants an award of punitive damages.

COUNT IX

FRAUD

296. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

297. Prior to Plaintiffs' use of NaturaLyte and/or GranuFlo and during the period in which Plaintiffs used NaturaLyte and/or GranuFlo, Defendants fraudulently suppressed material information regarding the safety and efficacy of these chemicals, including information regarding serious personal injuries and death. Furthermore, Defendants fraudulently concealed the safety information about the use of NaturaLyte and/or GranuFlo. As described above, NaturaLyte and/or GranuFlo have several well-known serious side-effects that are not seen in

other forms of dialysis chemicals. Plaintiffs believe the fraudulent misrepresentations described herein were intended to maintain and increase the sales volume of NaturaLyte and/or GranuFlo.

298. Defendants fraudulently concealed the safety issues associated with NaturaLyte and/or GranuFlo in order to induce physicians to recommend its use to Plaintiffs.

299. At the time Defendants concealed the facts that NaturaLyte and/or GranuFlo were not safe, Defendants were under a duty to communicate this information to Plaintiffs, physicians, the FDA, the medical community, and the general public in such a manner so that each group could appreciate the risks associated with using NaturaLyte and/or GranuFlo.

300. Defendants, at all times relevant hereto, withheld information from the FDA that they were required to report.

301. Plaintiffs and prescribing physicians relied upon the Defendants' outrageous untruths regarding the safety of NaturaLyte and/or GranuFlo.

302. Plaintiffs and/or their physicians were not provided with the necessary information by the Defendants.

303. NaturaLyte and/or GranuFlo were improperly marketed to Plaintiffs and/or their physicians as the Defendants did not provide proper instructions about how to use the NaturaLyte and/or GranuFlo and did not adequately warn about NaturaLyte and/or GranuFlo's risks.

304. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiffs and/or Plaintiffs' physicians, Defendants caused or contributed to Plaintiffs' injuries.

305. It is unconscionable and outrageous that Defendants would risk the lives of patients, including Plaintiffs. Nevertheless, the Defendants made conscious decisions not to

redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of NaturaLyte and/or GranuFlo. Defendants' outrageous conduct, which was wanton and willful, rises to the level necessary that Plaintiffs should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

306. Defendants widely advertised and promoted NaturaLyte and/or GranuFlo as safe and effective and/or as safe and effective for dialysis.

307. Defendants had a duty to disclose material information about serious side-effects to patients such as Plaintiffs.

308. Additionally, by virtue of Defendants' partial disclosures about these medications, in which Defendants touted NaturaLyte and/or GranuFlo as a safe and effective product, Defendants had a duty to disclose all facts about the risks associated with use of NaturaLyte and/or GranuFlo, including the risks described in this complaint. Defendants intentionally failed to fully disclose this information for the purpose of inducing physicians to prescribe and patients, such as Plaintiffs, to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

309. Had Plaintiffs been aware of the hazards associated with NaturaLyte and/or GranuFlo, Plaintiffs would not have used NaturaLyte and/or GranuFlo, which led proximately to Plaintiffs' injuries.

310. Defendants' advertisements regarding NaturaLyte and/or GranuFlo made material misrepresentations to the effect that NaturaLyte and/or GranuFlo were entirely safe, which misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing physicians to prescribe and patients, such as Plaintiffs, to receive and/or use NaturaLyte and/or

GranuFlo in dialysis treatment. Plaintiffs relied on these material misrepresentations when deciding to receive and/or use NaturaLyte and/or GranuFlo in dialysis treatment.

311. Upon information and belief, Plaintiffs aver that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with NaturaLyte and/or GranuFlo with the purpose of preventing physicians and patients, such as Plaintiffs, from discovering these hazards.

COUNT X

VIOLATION OF CONSUMER PROTECTION LAWS

312. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

313. Plaintiffs were administered NaturaLyte and/or GranuFlo during dialysis primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

314. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, user benefits, or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Over-promotion of the NaturaLyte and/or GranuFlo products, including but not limited to over-promotion of its safety and efficacy; and,

d. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

315. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of NaturaLyte and/or GranuFlo.

316. Defendants uniformly communicated the purported benefits of NaturaLyte and/or GranuFlo while failing to disclose the serious and dangerous side-effects related to the use of NaturaLyte and/or GranuFlo and of the true state of NaturaLyte and/or GranuFlo's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiffs in the marketing and advertising campaign described herein. Defendants' conduct in connection with NaturaLyte and/or GranuFlo was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of NaturaLyte and/or GranuFlo.

317. As a result of these violations of consumer protection laws, Plaintiffs have incurred serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

COUNT XI

LOSS OF CONSORTIUM

318. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

319. At all relevant times hereto, Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the Plaintiffs' injuries from NaturaLyte and/or GranuFlo.

320. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

321. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

322. For all Spouse Plaintiffs, Plaintiffs allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

323. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

324. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs, and/or intimate partners of the aforesaid Plaintiffs, have sustained and will continue to sustain severe physical injuries, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners jointly and severally for all

general, special and equitable relief to which Spouse Plaintiffs, Family Member Plaintiffs, and intimate partners are entitled by law.

COUNT XII

WRONGFUL DEATH

325. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

326. Plaintiffs Decedents' spouse, beneficiary and/or lawful representative of Decedents' Estate brings this claim on behalf of himself or herself and as the Decedents' lawful beneficiary. The Decedents' lawful beneficiaries include the Decedents' beneficiaries

327. As a direct and proximate result of the conduct of the Defendants and the defective nature of NaturaLyte and/or GranuFlo as outlined above, Decedents suffered bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

328. As a direct and proximate cause of the conduct of Defendants, Decedents' beneficiaries have incurred hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Plaintiffs, Administrators of Decedents' estates, bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to any and all relevant statutes.

COUNT XIII

SURVIVAL ACTION

329. Plaintiff incorporates by reference the allegations in paragraphs 1-233 as though set forth fully at length herein. Plaintiffs plead all Counts of this *Master Complaint and Jury Demand* in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiffs' resident State.

330. As a direct and proximate result of the conduct of Defendants, Decedents, prior to their deaths, were obligated to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Decedents were caused pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths; and, as a direct and proximate result of the aforesaid, Decedents suffered a loss of earnings and earning capacity. Plaintiffs' spouses, as Administrators of the Estates of Decedents, bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

331. As a direct and proximate result of the conduct of Defendants, Decedents and their spouses, until the time of Decedents' deaths, suffered a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estates of the Decedents pursuant to any and all applicable statutes or common law.

332. As a direct and proximate result of the conduct of Defendants, and including the observances of the suffering of the Decedents, until the date of their deaths, Plaintiffs suffered permanent and ongoing psychological damage.

333. As a direct and proximate result of the aforesaid, and including the observance of the suffering and physical deterioration of Decedents until the date of their deaths, Plaintiffs have

and will continue to suffer permanent and ongoing psychological damage which may require future psychological and medical treatment. Plaintiffs' spouses, as Administrators of the Estates of the Decedents, brings the claim on behalf of the Estates for damages any and all applicable statutes or common law and in their own right.

334. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs and the public.

335. As a result of the Defendants' conduct, the Plaintiffs suffered the injuries and damages specified herein.

336. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff(s) pray(s) for relief as follows:

1. Compensatory damages;

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering, loss of life's pleasures, lost wages, lost earning capacity, and impairment of earning capacity;

4. Damages for wrongful death;

5. Damages for survival;

6. Damages for Loss of Consortium;

7. Non-economic damages for an increased risk of future complications as a direct result of Plaintiff's injuries;

8. Punitive damages;

9. Prejudgment interest at the highest lawful rate allowed by law;

10. Interest on the judgment at the highest legal rate from the date of judgment until collected;

11. Attorneys' fees, expenses, and costs of this action; and,

12. Such further relief as this Court deems necessary, just and proper.

VII. JURY DEMAND

Plaintiffs hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

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